

Palliative Medicine Program
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Heal. Teach. Discover. Serve.

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June 1, 2001

Ms Kimberly Topper
Center for Drug Evaluation and Research (HFD-21)
Food and Drug Administration
5600 Fishers Lane
Rockville MD 20857

Dear Ms. Topper:

I believe that you will be involved in the Anesthetic and Life Support Drugs Advisory Committee meeting to be scheduled on June 14 and 15, 2001. It is my understanding that the committee will discuss the medical use of opioids for various patient populations, including those with chronic nonmalignant pain. As a medical oncologist and palliative medicine specialist, I am very interested in the outcome of this meeting.

My patients consist not only of those with cancer-related pain, but also individuals significantly impaired by chronic non-cancer-related pain syndromes. I also see patients with acute pain from multiple etiologies. The use of opioids for moderate to severe pain has played a major role in returning these individuals to a fully functional state in many cases and to a more functional state in others. As you are aware, there are other individuals whose lives are not enhanced by these drugs.

I believe that we are fortunate in this country to have the wide variety of opioids available for use in our patients. Opioid rotation – changing from one to the other - is a common practice when there are problems with side effects, compliance, cost, and other issues. Many of my patients require a high dose of opioids in order to become maximally functional. My preference would be to have more opioid medications available for patients with pain problems and not to have any further barriers that would interfere with their pain management.

It is realized that there is a problem with drug diversion and abuse of the opioid medications. There also is a problem with prescriptions for inappropriate uses of these medications. These problems had been present previously. Our patients are now able to obtain better pain relief with the medications that are currently available. Any increased legislative interference that would place more blockades in the appropriate use of these medications could be harmful to patients. Patients with fairly simple pain problems should be able to be managed by their primary care physicians. Pain and palliative medicine specialists, such as myself, can play a role in the management of the more difficult patients. Clearly there are not enough specialists or a broad enough geographic distribution of specialists to appropriately manage pain in an optimal fashion for the general public.

Ms. Kimberly Topper
5/24/01
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In short, I would request that our patients be given the capabilities of having adequate analgesics for pain management. Any deletion of currently available strong opioids or increase in regulations of these medications could be harmful in this regard.

Sincerely,

A handwritten signature in black ink, appearing to read "Neil M. Ellison". The signature is fluid and cursive, with the first name "Neil" being more prominent.

Neil M. Ellison, M.D.
Director, Palliative Medicine Program
Associate, Medical Oncology

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6/1/01